

CLAIMS

1. Vinflunine pharmaceutical composition,
characterized in that it is in the form of a
5 stable and sterile aqueous solution of a water-
soluble vinflunine salt at a pH of between 3 and
4.
2. Composition according to Claim 1, characterized in
10 that the vinflunine salt is vinflunine ditartrate.
3. Composition according to Claim 2, characterized in
that the composition consists of vinflunine
ditartrate and water for an injectable
15 preparation.
4. Composition according to Claim 1 or 2,
characterized in that it comprises a pH buffer
system in order to maintain the pH between 3 and
20 4.
5. Composition according to Claim 4, characterized in
that the molarity of the pH buffer system is
between 0.002 M and 0.2 M.
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6. Composition according to either of Claims 4 and 5,
characterized in that the pH buffer system
consists of an acetic acid/sodium acetate buffer
or a citric acid/sodium citrate buffer.
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7. Composition according to any one of Claims 2 to 6,
characterized in that the composition contains
vinflunine ditartrate with a base vinflunine
concentration of between 1 and 50 mg/ml,
35 advantageously between 25 and 30 mg/ml and in
particular 25 mg/ml.
8. Composition according to any one of Claims 2 to 7,
characterized in that it corresponds to one of the

following formulations: 68.35 mg of vinflunine ditartrate qs 2 ml in water or 136.70 mg of vinflunine ditartrate qs 4 ml of water or 341.75 mg of vinflunine ditartrate qs 10 ml of water, the vinflunine ditartrate corresponding, respectively, to 50 mg of base vinflunine, 100 mg of base vinflunine and 250 mg of base vinflunine.

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9. Composition according to any one of the preceding
10 claims, characterized in that it remains stable
for at least 36 months at $5^{\circ}\text{C} \pm 3^{\circ}\text{C}$.

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10. Use of a composition according to any one of
Claims 1 to 9, for the manufacture of a medicinal
product for parenteral administration,
advantageously via intravenous perfusion.

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11. Use according to Claim 10, characterized in that
the medicinal product is intended for treating
cancer.

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12. Process for preparing a composition according to
any one of Claims 1 to 9, comprising the following
successive steps:
- (a) dissolution of the vinflunine salt in water
for injectable preparations,
- (b) optional addition of a pH buffer,
- (c) sterilization by filtration of the bulk
solution,
30 - (d) aseptic distribution, under a nitrogen
atmosphere, of the sterile composition
obtained in step (c) in the container,
advantageously chosen from glass phials,
glass bottles and prefilled syringes.

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13. Packaging container containing the composition
according to any one of Claims 1 to 9.